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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,233	07/25/2001	Samuel J. Tremont	061765.00195	4337
22907	7590	02/25/2004	EXAMINER	
BANNER & WITCOFF 1001 G STREET N W SUITE 1100 WASHINGTON, DC 20001			COLEMAN, BRENDA LIBBY	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/912,233

Applicant(s)

TREMONT ET AL.

Examiner

Brenda L. Coleman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-162, 167, 188 and 205-265 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 226-236, 254, 261 and 264 is/are allowed.
- 6) ☒ Claim(s) 1-162, 167, 188, 205-225, 237-253, 255-260, 262, 263 and 265 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-162, 167, 188 and 205-265 are pending in the application.

This action is in response to applicants' amendment dated November 17, 2003. Claims 163-166, 168-187 and 189-204 have been canceled, claims 1-3, 8-10, 14, 29-31, 36-38, 42, 75-77, 82-84, 88, 121, 122, 125, 128, 141, 142, 145, 148, 167, 188, 205, 211, 230, 237, 241, 253, 255-256, 260 and 262 have been amended and claims 263-265 are newly added.

Response to Amendment

Applicant's amendments filed November 17, 2003 have been fully considered with the following effect:

1. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled d), r), u), w), x), y), z), aa), ab), ac), ad), ae), af), ag), ah), ag 2nd), ah 2nd), ai) and aj) maintained in the last office action, which are hereby withdrawn. However, with regards to the 35 U.S.C. § 112, second paragraph rejection labeled o) maintained in the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.

o) The applicant's stated that they have amended claims 14 and 88 to explicitly show that, in the penultimate structure shown for the R¹⁹ moieties, the nitrogen atom adjacent to the sulfonyl has a third bond to a hydrogen. However, this is not so.

Claims 14, 88 and (claims dependent thereon) are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point

out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

2. With regards to the 35 USC § 112, first paragraph rejection of claims 1-9, 14-37, 42-83, 88-124, 128-144, 148-225, 250-253 and 256-260 of the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicants stated that the amendment to claims 1-3, 8, 9, 29-31, 36, 37, 75-77, 82, 83, 121, 122, 141, 142 and 205 reciting " $N^+R^9R^{11}R^{12}A^-$ " as a substituent for alkyl, polyether, aryl, quaternary heterocyclyl, arylalkyl, heterocyclylalkyl, quaternary heterocyclylalkyl, alkylheterocyclylalkyl, and alkylaminoalkyl overcomes this rejection. The applicants point to paragraphs [129] and [131] (see p. 22-23) and in paragraphs [252] and [254] (see p. 54) for support for the specific amendment. However, the definition of R^{13} , R^{14} , and R^{15} on page 23 does not included the specific moieties described in the specification with respect to formula (I). The definition of R^{13} , R^{14} , and R^{15} in the additional embodiment where other variables in addition to R^{13} , R^{14} , and R^{15} are defined described a subgenus of the compounds of formula (I) which is not a description of the entire genus of formula I. Additionally, recent case law *Tronzo v. Biomet* 47 USPQ2d 1829 states that a species in a prior application does not provide written description to a generic claim.

Claims 1-9, 14-37, 42-83, 88-124, 128-144, 148-162, 167, 188, 205-225, 250-253, 256-260 and newly added claim 263 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

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inventor(s), at the time the application was filed, had possession of the claimed invention. For reasons of record and stated above.

3. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejections of claims 1-225, 250-253 and 256-260 of the last office action, which are hereby **withdrawn**.

4. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled a), d), e), f), g), h), i), j), k), l), m), n), o), p), q), r), s), t) and u) of the last office action, which are hereby withdrawn. However, with regards to the 35 U.S.C. § 112, second paragraph rejection labeled b) and c) of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.

b-c) The applicant's stated that they have amended claim 9 to delete the slash marks which appear through a hyphen in two locations within the claim.

However, this is not so.

Claims 9 and (claims dependent thereon) are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

5. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejection of claims 163-166, 168-187, 189-204, 253 and 260 of the last office action, which is hereby **withdrawn**.

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In view of the amendment dated November 17, 2003, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-9, 14-35, 42-81, 88-124, 128-144, 148-162, 250-252 and 256-259 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment with respect to the definition of R⁹ and R¹⁰ where R⁹ and R¹⁰ are independently selected from carboxyalkylheterocycle is not described in the specification for the genus. See pages 3, 8, 14, 31, 35, 41, 60, 65, 71, 90, 96, 105 and 112 of the amendment.

Applicant is required to cancel the new matter in the reply to this Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 1-162, 167, 188, 205-225, 237-253 and 255-260, 262, 263 and 265 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reason(s) apply:

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- a) Claims 1-3, 8, 9, 29-31, 36, 37, 75, 76, 77, 82, 83, 121, 122, 141, 142, 167, 188, 205 (and claims dependent thereon) are vague and indefinite in that it is not known what is meant by the moiety $-N^+R^7R^8R^9A^-$ which is a **divalent** substituent. See pages 3, 8, 14, 18, 21, 31, 35, 41, 45, 48, 60, 65, 71, 74, 77, 89, 96, 105, 111, 122, 127 and 132
- b) Claim 1 (and claims dependent thereon) are vague and indefinite in that it is not known what is meant by the moiety $-N^+R^7R^8A^-$ which is a **monovalent** moiety of R^5 . See page 3.
- c) Claims 1-3, 29-31, 75, 76, 77, 121, 122, 141, 142 (and claims dependent thereon) are vague and indefinite in that it is not known what is meant by the compound **carboxyalkylheterocycle** in the definition of R^9 and R^{10} . See pages 3, 8, 14, 31, 35, 41, 60, 65, 71, 90, 96, 105 and 112
- d) Claims 1, 29, 75, 167, 188, 205 (and claims dependent thereon) are vague and indefinite in that it is not known what is meant by the moiety OM in the definition of the substituents on the R^6 quaternary heterocyclyl radical, which fails to indicate the point of attachment. See pages 6, 33, 63, 125, 130 and 135
- e) Claims 1, 29, 75, 167, 188, 205 (and claims dependent thereon) are vague and indefinite in that it is not known what is meant by the moiety $PR^{13}R^{14}$ in the definition of R^6 radicals comprising carbon, which fails to indicate the point of attachment. See pages 6, 33, 63, 125, 130 and 135
- f) Claims 10, 12, 13, 38-41, 43-58, 84-87, 89-104, 125-127, 135-140, 145-147, 155-160, 250-252 and 256-259 are vague and indefinite in that it is not known what

is meant by an alkyl optionally replaced by $N^+R^9R^{10}A^-$. See pages 23, 50, 51, 79, 80, 99 and 114.

g) Claims 75-120, 250, 256 and 257 are vague and indefinite in that it is not known what is meant by the proviso of R^5 where R^5 is $-OR^9$ substituted by $-O(CH_2)_1$. $4N^+R'R''R'''A^-$, since it is not seen when $-OR^9$ is ever substituted by $-O(CH_2)_1$. $4N^+R'R''R'''A^-$. See page 64.

h) Claims 167, 188, 205, 253, 260 and 263 are vague and indefinite in that it is not known what is meant by the variable n , which is not defined. See pages 125, 130 and 135.

i) Claims 188, 253 and 260 are vague and indefinite in that it is not known what is meant by the moiety $-N^+R^9R^{10}R^wA$ in the definition of the substituents of R^{13} , R^{14} and R^{15} . See page 129.

k) Claims 205-225, 253, 260 and 263 are vague and indefinite in that it is dependent upon a canceled claim. See page 131.

l) Claims 237-249, 255, 262 and 265 are vague and indefinite in that it is not known what is meant by the two formulae called Formula IX. See page 157.

Allowable Subject Matter

8. Claims 226-229 and 231-236 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00 Monday - Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting -SPE of 1624 at 571-272-0661.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Brenda Coleman
Primary Examiner Art Unit 1624
February 20, 2004